



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/835,482	04/08/97	RUBIN	A 002

GILDO E FATO
515 ASH STREET
LIBERTYVILLE IL 60048

HM42/0904

EXAMINER
SEIDLECK, B

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/04/98 ⁹

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

08/835,482

Applicant(s)

Rubin

Examiner

Brian K. Seidleck

Group Art Unit

1615



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Papers Received

1. Receipt is acknowledged of applicant's IDS filed on 7/7/97.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-10 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The examiner is of the opinion that the present invention's novelty lies with the release profile and its claimed ability to prevent fluctuations in plasma levels. See specification at page 1. However, no data has been provided which demonstrates the claimed novelty of the invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 4 and 10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 4, the phrase "excipient layer" renders the claim indefinite because it is unclear from the claim and the specification the meaning of the term.

In addition, in claim 10, the term "adjacent to" is unclear to the examiner whether the layers are in contact with another or are separated by a third layer.

Claim Rejections - 35 U.S.C. § 103

6. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Dempski et al (U.S. Pat. No. 4,900,755, collectively "Dempski") and Conte et al (U.S. Pat. No. 5,738,874, collectively "Conte").

Dempski teaches the combination of levodopa and carbidopa in a sustained release formulation. See abstract. The combination is well known in the art for the treatment of Parkinson's disease. A commercial product which includes this combination is Sinemet®. The art recognizes the importance of treating Parkinson's disease with a dosage form which prevents the

emergence of "wearing-off" and "on-off" phenomena. See Dempski at Cols. 1-2. As to the overall concentrations of the drugs, Dempski teaches overlapping ranges at Col. 3, lines 45-60. Such doses will vary depending on the weight, age and severity of the condition being treated.

Conte teaches a pharmaceutical tablet capable of releasing one or more drugs at different release rates. See abstract. The first layer contains one or more drugs with an immediate release profile and a second layer containing one or more drugs with a sustained release profile. *Id.* Conte teaches both levodopa and carbidopa. See Col. 18, claim 6. An optional barrier can be placed between the first and second layers. See abstract. Conte teaches combination therapy with both levodopa and carbidopa in a formulation with multiple release profiles. See Cols. 2-3. As to the specific amounts of drug active, the examiner relies on the teachings of Dempski above. The examiner is of the opinion that unless demonstrated otherwise, the amounts used in the present are known in the art for treating Parkinson's and it would have been obvious for one skilled in the art to regulate the dosage based on the individual patient being treated.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Edgren et al (U.S. Pat. No. 5,192,550); Wenzel et al (WO 92/12710); Di Rocco et al (U.S. Pat. No. 5,496,836); Berliner et al (U.S. Pat. No. 5,210,076); and Edgren et al (U.S. Pat. No. 5,221,536).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Brian K. Seidleck** whose telephone number is **(703) 305-4448**. The examiner can normally be reached **Monday through Friday from 6:30am to 3:00pm**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K. Page**, can be reached on **(703) 308-2927**. The official fax numbers for Technology Center 1600 are **(703) 305-3592** and **(703) 308-4556**. The unofficial fax number is **(703) 308-7924**.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[thurman.page@uspto.gov]**.

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the **Technology Center receptionist** whose telephone number is **(703) 308-1235** or **(703) 308-1234**.

Brian K. Seidleck
Patent Examiner
September 1, 1998